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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,304	12/22/2000	Julio C. Palmaz	6006-019	3650

7590

04/01/2004

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,304

Applicant(s)

PALMAZ ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-38 and 41-50 is/are rejected.
- 7) ☒ Claim(s) 39,40 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/15/04, 2/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Information Disclosure Statement***

The information disclosure statement filed January 15, 2004 has been considered by the examiner. The information disclosure statement filed February 19, 2004 is a duplicate copy of the statement filed on January 15, 2004, therefore a duplicate copy was not signed, because the references have already been considered.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 10-11, and 14-26 have been considered but are moot in view of the new ground(s) of rejection. However, the examiner would like to address one of the applicant's arguments, seeing that it applies to the current office action. Applicant has argued that the previously applied patents, for instance Clubb (USPN 6,203,732 B1) and Roth (USPN 6,096,195) do not disclose a condition/rate that controls of the formation of heterogeneities in a material. The examiner disagrees. First, every material has a certain grain size, grain phase, composition, and binding sites. Therefore, when a user *selects* a material to be deposited, the user is selecting (thus controlling) the formation of these heterogeneities, which are specific to the material of selection. Because Clubb and Roth disclose specific materials to be deposited, the user is controlling the heterogeneities by selecting a material, each material having known grain size, phase, composition, and binding sites specific to that material. Second, not only is the user controlling formation of heterogeneities by selection of a material, but also is controlling the formation of heterogeneities by depositing under a specific condition/rate. Every deposition process is completed at a rate and under a condition. Every rate, or condition is inherently going to have some kind of effect on the heterogeneity of the material. A rate, or

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condition, is a variable, and every variable will have some effect on the heterogeneity of the material, whether it be zero, a little, or a lot. It is noted that the applicant has not claimed a heterogeneous material, the applicant has only claimed a *condition/rate* that has *control* over the formation of heterogeneities. And since every condition/rate has some effect over the end product of the deposition process, every deposition process, including the process of Clubb and Roth, have a condition and rate, each condition/rate inherently having control over the formation of heterogeneities, because all condition/rates have an effect on the heterogeneity of the material, and the selection of a condition or rate, is controlling what heterogeneities form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-37 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 27, the applicant recites, "rate that controls a formation of *heterogeneities* to form a generally tubular, unpatterned, substantially *homogeneous* metal film". It is unclear to the examiner how a material can be heterogeneous and homogeneous at the same time. Appropriate correction or clarification is required. Also, when applicant recites, "controls a formation of heterogeneities", it is unclear *what* the heterogeneities are formed *in*. Claims 28-37 depend upon claim 27 and inherit all problems associated with the claim.

Claim 35 recites the limitation "the deposition chamber pressure" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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Claim 37 recites the limitation "the substrate temperature" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Referring to claims 44-46, the claims recite, "An implantable medical device produced according to the method of Claim 38". Claims 44-46 appear to be product claims depending from independent method claim 38. Independent claim 38 has defined the scope of the claim by the preamble "A method of making an implantable medical device". All claims dependent from independent claim 38 should include the same preamble (The method according to claim 38), in order to stay within the scope of the claim. Claims 44-46 have left the scope of the claim. The preambles of claims 44-46 require correction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38, 41, and 43-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Clubb et al. (USPN 6,203,732 B1, cited in previous office action). Clubb discloses a method of making an implantable medical device comprising the steps of providing a substrate (10) having a shaped exterior surface (12) capable of accommodating metal deposition thereupon, vacuum depositing (col.5, lines 35-46) a biocompatible material (20) onto the shaped exterior surface of the substrate (10) at a deposition rate, with a substrate temperature, and at a deposition chamber pressure (deposition is disclosed to occur, therefore, inherently there is some rate, pressure and

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temperature the deposition is occurring at) that controls a formation of heterogeneities (every condition/rate will have an effect on the heterogeneity of the material, thus, is a controlling factor, see also response to arguments above) on a surface of a biocompatible material layer (20), and forming the implantable device (100) from the deposited biocompatible material (20).

Clubb discloses imparting a pattern (100c) onto the exterior surface (12) of a cylindrical substrate (10), wherein the pattern (100c) is transferred to the biocompatible material layer (20). Clubb discloses control of heterogeneities forming a homogeneous surface (uniform surface 20, seen in figure 14, and also uniform surface 103, seen in figure 18), wherein the implantable device (100) comprises a stent capable of radial expansion by shape memory, pseudoelastic, plastic, or elastic deformation, and the stent having a plurality of openings (between ribs 104, 106). Clubb discloses control of heterogeneities such as grain size, grain phase, material composition, surface topography, polar and non-polar binding sites, fatigue life, corrosion resistance, tensile strength, and yield strength of the biomaterial (these properties are inherently controlled by the user when the user selects a material and condition to deposit, which have an effect on the material properties, see also response to arguments above).

Claims 38, 41-42, and 44-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Roth (USPN 6,096,175, cited by applicant in IDS). Roth discloses a method of making an implantable medical device (fig.2) comprising the steps of providing a substrate (36) having a shaped exterior surface (exterior surface has a flat rectangular shape) capable of accommodating metal deposition thereupon, vacuum depositing (col.5, lines 25-30) a biocompatible material (42) onto the shaped exterior surface of the substrate (36) at a deposition rate, with a substrate

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temperature, and at a deposition chamber pressure (deposition is disclosed to occur, therefore, inherently there is some rate, pressure and temperature the deposition is occurring at) that controls a formation of heterogeneities (every condition/rate will have an effect on the heterogeneity of the material, thus, is a controlling factor, see also response to arguments above) on a surface of a biocompatible material layer (42), and forming the implantable device (1) from the deposited biocompatible material.

Roth discloses imparting a pattern onto the exterior surface of a substrate (col.8, lines 6-8), wherein the pattern is transferred to the biocompatible material layer. Roth discloses depositing a sacrificial material layer (50) onto the substrate (36) prior to deposition and removing the sacrificial layer in order to remove the medical device from the substrate (fig.4). Roth discloses control of heterogeneities forming a homogeneous surface, wherein the implantable device comprises a stent (1) capable of radial expansion by shape memory (shape memory materials, col.6, lines 5-18), pseudoelastic, plastic, or elastic deformation, and the stent having a plurality of openings. Roth discloses control of heterogeneities such as grain size, grain phase, material composition, surface topography, polar and non-polar binding sites, fatigue life, corrosion resistance, tensile strength, and yield strength of the biomaterial (these properties are inherently controlled by the user when the user selects a material and condition to deposit, which have an effect on the material properties, see also response to arguments above).

Allowable Subject Matter

Claim 27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

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Claims 28-37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 39, 40, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

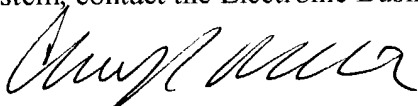
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

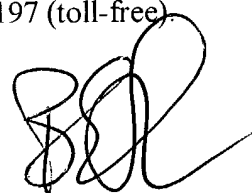
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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